

Meiji Seika Pharma Co., Ltd.

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Meiji completed Phase I studies and moves onto Phase II study of ME3183, a selective PDE4 inhibitor for the treatment of psoriasis

Meiji Seika Pharma Co., Ltd.* (Headquarters: Tokyo, President and Representative Director: Daikichiro Kobayashi, hereinafter “Meiji”) today announced that it has successfully completed Phase I clinical trials of ME3183, a selective PDE4 inhibitor, conducted in the United States. ME3183 has been shown to be safe and well-tolerated across the doses tested. Based on these results, Meiji plans to initiate a Phase II clinical trial in patients with plaque psoriasis in the United States and Canada in the first quarter of 2022.

ME3183 is an orally-available and selective inhibitor for phosphodiesterase 4 (PDE4) discovered by Meiji. In non-clinical studies, ME3183 showed greater anti-inflammatory effect and its inhibitory effect of TNF- α production was approximately 30 fold greater than an existing orally-available PDE4 inhibitor for psoriasis. The distribution of ME3183 in brain was sufficiently low.

The Phase I single and multiple dose clinical trials were conducted in healthy volunteers in the United States. ME3183 has been shown to be safe and well-tolerated across the doses which exceeded the anticipated effective exposures expected from the non-clinical data. The results suggest that ME3183 can exert higher clinical efficacy than existing PDE4 inhibitors at the higher dose settings.

The Phase II clinical trial is planned to be conducted in patients with plaque psoriasis in the United States and Canada in order to confirm the potential of ME3183 as the best-in-class orally-available PDE4 inhibitor. Meiji Pharma USA Inc., a wholly owned subsidiary of Meiji, will be in charge of the Phase II clinical trial.

Meiji strives to provide efficacious and safe treatment for unmet medical needs, such as psoriasis and autoimmune diseases.

*: For further information, please visit the website at: <https://www.meiji.com/global/about-us/corporate-profile/meiji-seika-pharma/>